K112534
1/2

III. 510(K) SUMMARY

AUG 10 2012

LifeCell Tissue Expander

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

LifeCell Corporation
One Millennium Way
Branchburg, NJ 08876
Phone: (908) 947-1116 or (908) 947-1114
Facsimile: (908) 947-1095
Email: kmeany@lifecell.com or skalinani@lifecell.com

Contact Person: Kristen Meany, CQA, RAC or Sadhana Kalinani

Date Prepared: August 31, 2011

Date Revised: August 10, 2012

Name of Device and Name/Address of Sponsor

LifeCell Tissue Expander

LifeCell Corporation
One Millennium Way
Branchburg, NJ 08876

Common or Usual Name

Tissue Expander

Classification Regulation

LCJ (Unclassified)

Predicate Device

Allergan Medical
NATRELLE® 133 Tissue Expander with Suture Tabs (K102806)

Intended Use / Indications for Use

The LifeCell Tissue Expanders are intended for use in breast reconstruction following mastectomy, treatment of underdeveloped breasts, and treatment of soft tissue deformities. The LifeCell Tissue Expanders are intended for temporary subdermal implantation and are not intended for use beyond six months.

Technological Characteristics

The LifeCell Tissue Expander is composed primarily of silicone elastomers. The predicate device and the LifeCell Tissue Expander utilize the same fundamental technology:

- A silicone expansion shell with a smooth or textured surface which expands with sequential injections of sterile saline
- An injection site, a magnetic locating system, a titanium needle guard, and suture tabs

The LifeCell Tissue Expander is provided sterile and its packaging consists of an inner polycarbonate thermoform tray, containing a tissue expander, sealed with Tyvek® lidstock. The sealed inner tray is placed inside a sterile barrier system which is composed of an outer polycarbonate tray that is then sealed with a Tyvek® lid. The LifeCell Tissue Expander is available in multiple styles and sizes, and each product is labeled accordingly.

Performance Data

The LifeCell Tissue Expander has undergone biocompatibility and preclinical testing including tensile strength, percent elongation, tensile set, joint strength testing, overexpansion testing, injection port testing and tissue expander injection port competency over time testing. The data demonstrates the LifeCell Tissue Expander possesses sufficient material and functional properties for the intended use.

Substantial Equivalence

The LifeCell Tissue Expander is substantially equivalent to a legally marketed predicate device, NATRELLE® 133 Tissue Expander with Suture Tabs (K102806). The LifeCell Tissue Expander has the same intended uses and indications for use, and similar technological characteristics and principles of operation as the predicate device. Performance data demonstrate that the LifeCell Tissue Expander functions equivalently to the predicate device. Thus, the LifeCell Tissue Expander is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

AUG 10 2012

Lifecell Corporation
% Ms. Kristen Meany, CQA, RAC
One Millenum Way
Branchburg, New Jersey 08876

Re: K112534
Trade/Device Name: LifeCell Tissue Expander
Regulatory Class: Unclassified
Product Code: LCJ
Dated: August 09, 2012
Received: August 10, 2012

Dear Ms. Meany:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K112534

II. INDICATIONS FOR USE STATEMENT

510(k) Number (if known):_____

Device Name: LifeCell Tissue Expander

Indications for Use:

The LifeCell Tissue Expanders are intended for use in breast reconstruction following mastectomy, treatment of underdeveloped breasts, and treatment of soft tissue deformities. The LifeCell Tissue Expanders are intended for temporary subdermal implantation and are not intended for use beyond six months.

Prescription Use X AND/OR Over-The-Counter Use____
(Part 21 C.F.R. 801 Subpart D) (21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for David Krause

Page ____ of ____

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K112534